PATIENT MONITOR

PM 50

MANUAL BOOK

Elitech®
TECHNOVISION

Foreword

Please read the Manual carefully before using this product. The Manual explaining the operating procedure must be followed strictly. This detailed guide introduces the steps to be taken when using the product, operations that may result in abnormality, the risk of causing personal injury and damage to the product and other content, see chapter for details. Anomalies or personal injury and device damage arising from the use, maintenance, storage do not follow the requirements of the Manual, our company is not responsible for the guarantee of safety, reliability and performance! The manufacturer's warranty service does not cover such faults!

Our company has factory records and user profiles for each device, users get one year free maintenance service from the date of purchase. To make it easier for us to provide you with comprehensive and efficient maintenance services, be sure to return the warranty card when you need repair service.

Note: Please read the Manual carefully before using this product.

Described in this Manual according to the technical situation of the product. In the case of software modifications and enhancements, the information contained in this document is subject to change without notice.

Warning items

Before using this product, you should consider the safety and efficacy described below:

- Each measurement result is explained in combination with clinical symptoms by a qualified doctor.
- Reliability and operability using the product whether it meets the appropriate Manuals related to maintenance instructions.
- The intended operator of this product may be the patient.
- Do not perform maintenance and service while the device is in use.

Operator's responsibility

- The operator must carefully read the Manual before using this product, and strictly follow the operating procedures of the Manual.
- Fully consider the safety requirements when designing the product, but the operator should not neglect the observation of the patient and the state of the machine.
- The operator has the responsibility to provide our company with the conditions of use of the product.

Responsibility for our company

- Our company has a responsibility to provide quality products that match the company standard of this product.
- Our company will provide circuit diagrams, calibration methods and other information upon user's request to assist suitable and qualified technicians to repair the parts designated by our company.
- Our company has the responsibility to complete product maintenance according to the contract.
- Our company has a responsibility to respond to user needs in a timely manner.
- In the following cases, our company is responsible for the impact on the safety, reliability and performance of the device:

Assembly, addition, debugging, modification or repair is carried out by personnel approved by our company.

The electrical facilities in the room have met the relevant requirements and the equipment is used according to the Manual.

CONTENTS

Chapter 1 Introduction

Operators do not require professional training, but should use this product after fully understanding the requirements in this manual.

In order to prevent users from suffering injury or loss due to improper use, please refer to " **Precautions** " and use this product properly.

For an overall introduction to Blood Pressure Monitoring, please refer to **General Information.**

For basic operating instructions, see **Key Functions.**

For interface socket allocation, please refer to **Interfaces.**

1.1 Precautions

⚠ Warning ⚠

- **If not used properly, there is a possibility of damage to personnel and property.**
- **Damage to property means damage to homes, property, domestic animals and pets.**
- **For acute blood circulation disorders or arrhythmic patients, please use the device under the supervision of a doctor. Otherwise, it may cause acute bleeding, or measurement error due to pinched arm.**
- **You should not take NIBP measurements on patients with sickle cell disease or in any condition whose skin is damaged or expected to be damaged.**

- **For thrombasthemic patients, it is important to determine whether blood pressure measurements should be automated. Determination should be based on clinical evaluation.**

⚠ Contraindications ⚠

There are no contraindications.

⚠ Warning ⚠

Do not use the device if flammable anesthetic gas is mixed with air or nitrous oxide.

Otherwise, it may lead to risk.

For children and people who cannot express themselves, please use the device under the supervision of a doctor.

Otherwise, it may cause accidents or disputes.

Self-diagnosis and treatment using measurable results may be dangerous. Follow your doctor's instructions.

Please provide the measurement results to a doctor who knows your health and accepts the diagnosis.

Please do not use for any other purpose except blood pressure measurement.

Otherwise, it may cause accidents or obstacles

Please use special cuffs.

Otherwise, the measurement results may be incorrect.

Please do not leave the cuff in an overly high state for a long time.

Otherwise, it may lead to risk.

If liquid splashes onto the device or accessories, especially when liquid may enter the tubing or device, stop use and contact service.

Otherwise, it may lead to risk.

Dispose of packaging materials, comply with applicable waste control regulations and keep out of reach of children.

Otherwise, it may cause harm to the environment or children.

Please use approved accessories for the device and check that the device and accessories are functioning properly and safely before use.

Otherwise, measurement results may be inaccurate or accidents may occur.

When the device is accidentally damp, the unit should be placed in a dry and ventilated place for a certain period of time to remove moisture.

Otherwise, the device may be damaged by moisture.

Do not store and transport the device outside the specified environment.

Otherwise, it may cause measurement error.

It is recommended that you regularly check for damage to your device or accessories, if you find any damage, stop using it, and contact a hospital biomedical technician or our Customer Service immediately. Do not disassemble, repair, and modify the device without permission. Otherwise, it cannot be measured accurately.

This device cannot be used on mobile transport platforms.

Otherwise, it may cause measurement error.

This device cannot be used on an inclined table.

Otherwise, there is a risk of falling.

Dispose of packaging materials, used batteries and end-of-life products in accordance with local laws and regulations. Expired products and materials are properly disposed of by users according to the decision of the authorities.

Replacing accessories not provided by our company may result in errors. Without our company or other approved maintenance organization, trained service personnel should not attempt to maintain the product.

This device can only be used for one test object at a time.

If small parts of the device are inhaled or swallowed, please consult a doctor immediately.

Devices and accessories are processed with allergenic materials. If you are allergic to it, stop using this product.

Do not use the cell phone near a blood pressure monitor. The excessive radiation field generated by mobile phones may interfere with normal use of blood pressure monitors. The blood pressure monitor has a small amount of electromagnetic radiation to the external environment, but it does not affect the normal use of other equipment.

This device is suitable for operations with electrosurgery equipment, but when used with electrosurgery equipment, patient safety must be a priority.

The parts of the device that come into contact with the patient (cuff, air tube, shield, etc.) are made of insulating material and the device is protected against electric shock. When a high frequency/defibrillation device is used on a patient, no special precautions are required and the use of defibrillation does not affect the device.

If Luer lock connectors are used in pipe construction, there is a possibility that they may be inadvertently connected to the intravascular fluid system, allowing air to be pumped into the blood vessels.

This device is suitable for operations with electrosurgery equipment, but when used with electrosurgery equipment, patient safety must be a priority.

When the monitor gets wet, please stop using it and contact us.

After pressing the power button, if the device has display errors such as white screen, blurry screen or no display content, please contact our company.

⚠ Notes ⚠

- **The software is developed according to IEC60601-1. The possibility of harm arising from errors in the software has been minimized.**
- **All analog and digital equipment connected to this device must be certified to IEC standards (such as IEC60950: Information technology equipment -Safety and IEC60601-1: Medical electrical equipment-Safety), and all equipment must be connected in accordance with the requirements of a valid version of the IEC60601 system standard. -1-1. The person connecting additional equipment to the signal input and output ports is responsible for whether the system complies with the IEC60601-1 standard.**
- **See the next chapter for minimum values for the patient's physiological signals. Operation of the device below the minimum value may result in inaccurate results.**
- **Monitors must comply with IEC 80601-2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers**.

1.1 General Information

The monitor not only measures outpatient blood pressure, but also monitors NIBP and SpO2

parameters. The monitor integrates parameter measurement module function and display function in one device, features in compactness and light weight, the monitor is suitable for pregnant women. The POWER button is on the front panel. The RUN indicator and PROMPT indicator at the bottom of the screen flash once when the device is turned on. The PROMPT indicator flashes when the prompt appears. The cuff and the SpO2 probe socket are located on the top of the device. The USB socket is at the bottom of the monitor.

This monitor has a friendly operating interfaces, all operations can be completed by buttons on the front panel. (See "Key Functions" for details)

Outpatient blood pressure measurement function:

In this mode, the monitor can work 24 hours continuously. The monitor can upload data to PC for data editing, trend chart editing, statistics, information display, diagnosis information editing, various parameter settings, printing and other functions.

Monitoring function:

NIBP systolic pressure (SYS), diastolic pressure (DIA), mean pressure (MAP)

Oxygen saturation SpO2 (SpO2), pulse (PR), SpO2 PLETH

⚠ **Notes** ⚠

In this mode, the length of continuous working time is determined by the measurement interval set by the user.

It is useful that the software on the state of monitoring as an outpatient blood pressure. See Software Functions for details.

1.2 Button Function

Users can switch the interface with buttons to achieve the functions of parameter setting, blood pressure measurement, SpO2 measurement and result checking, the detailed functions for each button are:

as follows:

-  Power Button

ON/OFF: long press to turn on/off the device.

Shortcut function: in any interface, short press to quickly return to the main interface.

Notes

When the battery power is low, a prompt appears. The battery frame turns red, and flashes non-stop.

-  Menu Button

In any interface, press to execute the selected function.

-  Up Button

Main interface: if the voice prompt is "ON" ( displayed in the upper left corner), short press to switch between prompt and silent ( displayed in the upper left corner). Another interface: select item to top or page turner.

- Down Button

Select item down or page turner.

- Measurement Button

Press to inflate the cuff to measure blood pressure. During measurement, press to stop measuring and deflate.

Notes

The yellow rectangle that moves with the selection of the UP and DOWN buttons on the interface is the cursor, and any place where the cursor can remain operable. When selecting content with the menu button, the cursor turns red, then press the UP/DOWN button to select, press the MENU button again to exit the selected state and complete the parameter setting.

Notes

Plug in the USB to continue uploading and downloading data when there is no battery. That

the top of the screen displays the USB symbol indicates the instrument is successfully connected to the computer. Invalid NIBP key when plugging in USB line.

1.4 External Interface

For convenient operation, different types of interfaces exist in different parts of the monitor.

(1) At the top is the Socket for the SpO2 Sensor and the socket for the NIBP cuff.

⚠ Notes ⚠

The NIBP airway tube has been attached to the Socket for the NIBP cuff.

① Socket for NIBP cuff

② Socket for SpO2 Sensor Sensor

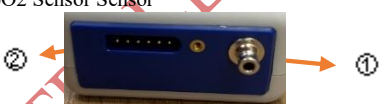


Figure 1.3.1 Top view

(2) At the bottom is the USB socket

①Connector for USB, connect data line to upload data.

Figure 1.3.2 Bottom View

1.5 Accessories

1) Cufflinks for adults
2) USB data cable
3) SpO2 probe
4) Manual

⚠ **Notes** ⚠

Please use the accessories provided by the manufacturer or replace the accessories according to the manufacturer's requirements to avoid harm to the patient.

⚠ **Notes** ⚠

The cuff width should be 40% of the *limb circumference* (50% for newborns) or 2/3 of the

length of the upper arm. The length of the inflated cuff should be sufficient to encircle 50% to 80% of the limb. Incorrect cuffs can result in incorrect readings. If there is a problem with the cuff size, use a larger cuff to reduce the error.

Patient type	*limb* circumference	Cuff Width	Tube length
Adult 1	25～35 cm	14 cm	1.5 m or 3 m
Adult 2	33～47 cm	17 cm	

Neonatal disposable cuffs

Warning

Please use the special accessories provided by the manufacturer or replace the accessories according to the manufacturer's requirements to avoid causing harm to the patient.

Notes

- Cufflinks are consumables. In order to measure blood pressure correctly, please change the cuff in time.
- If the cuff leaks, please contact our company to buy a new one. Cuffs purchased separately do not include the BP extension tube. Please explain if you need to buy BP extension tube at the same time. If you don't want to buy a BP extension tube, don't throw away the BP extension tube when changing the cuff, put it in a new cuff.

- Pockets will make it convenient for users to carry the monitor. There is no need to replace it when the backpack is slightly worn. Patients can contact our company to purchase a new backpack when the original backpack cannot carry the monitor.

⚠ Notes ⚠

At the end of its useful life, the product described in this manual, as well as its accessories, must be disposed of in accordance with the guidelines governing the disposal of that product. If you have any questions regarding product disposal, please contact us or a representative.

Chapter 2 Getting Started

2.1 Unpacking and Checking

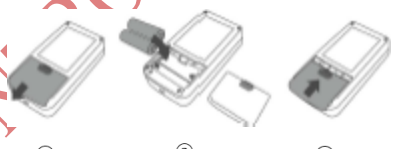
Unpack and remove equipment and accessories carefully. Save the packaging for possible future transportation or storage. Check the components according to the packing list.

- Check for mechanical damage.
- Check all cables, modules and accessories.

If there is a problem, contact the distributor immediately.

2.2 Battery Installation

The instrument will be equipped with two 'AA' or high capacites batteries. Before using the instrument, you must insert the battery into the battery case on the back of the Monitor.



① Remove the battery cover in the direction of the arrow.

② Install the "AA" battery according to the ⊕⊖ polarity.

③ Slide to close the battery cover.

Icon “ ”: the battery will run out, a “Low Battery” *prompt will appear* simultaneously. Replace with two new batteries (same type) immediately. Test at low power may cause data drift and other problems.

⚠ **Attention** ⚠

- Turn off the unit before replacing the battery.
- Please use 2 "AA" size batteries, do not use other types of batteries. Otherwise, it may cause a fire.
- New and old batteries, different types of batteries cannot be used. Otherwise, the battery may leak, heat, break, and damage the monitor.
- The battery polarity "+" and "-" must match the polarity of the battery compartment as shown. If the battery runs out, replace it with 2 new batteries at the same time.
- Please remove the battery if the device is not used for a long time (more than ten days). Otherwise, the battery may leak, heat, break, and damage the monitor.
- If battery electrolyte gets in your eyes, rinse immediately with plenty of clean water. Call the doctor immediately. Otherwise, it will cause blindness or other harm.

- If battery electrolyte sticks to skin or clothing, please rinse immediately with plenty of clean water. Otherwise, it may injure the skin.
- Dispose of discharged batteries in accordance with applicable local environmental regulations. Otherwise, it will cause environmental pollution.
- Monitor is internal powered equipment, can be connected to public network.

2.3 Turn on the Instrument

Hold down the power button  , the indicator will flash once, the system will successfully enter the main interface. The backlight is always on in monitoring and blood pressure mode. In ABPM mode, the backlight will be turned off according to the backlight time when there is no operation button, press any button to lighten the screen.

Warning

If any signs of damage are detected, or the instrument displays multiple error messages, do not use it on any patient. Contact a biomedical technician at the hospital or our Customer Care Center immediately.

The device can be used normally after power on, without waiting for the device to be set up.

Notes

Check all functions that may be used and make sure the device is in good condition.

2.4 Connect the SpO2 Probe

Connect the necessary sensors to the monitor and patient monitoring area. For blood pressure measurement, insert one end of the cuff into the socket of the NIBP cuff and place the other end on the patient's upper arm. For Sp02 measurement, insert one end of the sensor into the Sp02 socket and hold the other end with a finger. As shown below: Connect the sensor between the Monitor and the patient measuring section.

Chapter 3 Function Interface

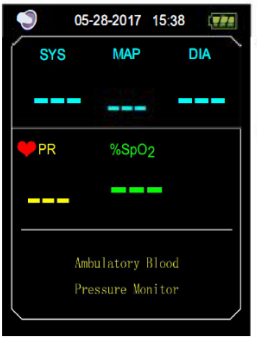
3.1 Main Interface

Turn on the power switch, the indicator will flash once, the system will successfully enter the main interface.

In ABPM mode, if there is no button operation within the time set in the BACKLIGHT TIME item, the monitor will turn off the LCD and enter standby mode. The RUN indicator light flashes once every 2 seconds, indicating the monitor is in working mode. "Ambulatory Blood Pressure Monitor" information is displayed at the bottom of the main interface.

Monitoring mode and BP mode: The "BACKLIGHT TIME" setting is invalid. Information "Sp02 Sensor off!" is displayed at the bottom of the main interface, "PM" is displayed at the bottom.

Under BP mode, the "BACKLIGHT TIME" setting is invalid, the backlight is always bright. Information "Sp02 Sensor off!" displayed at the bottom of the main interface. As shown below:



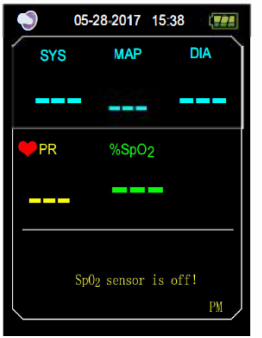


Figure 3.1.1 Main Menu ABPM Figure 3.1.2 Main Menu Monitoring Figure 3.1.3 Main Menu BPM

After the measurement, the patient's measurement results will be displayed, with a description as below:

SYS : Systolic pressure
MAP : Mean pressure
DIA : Diastolic pressure
PR : Pulse
%SpO2 : Oxygen saturation

Pressure values can be compared on this interface: connect the NIBP Simulator with the unit, long press the “Measure” button for 5 seconds to enter the real-time pressure comparison mode to compare the measured pressure values with the unit and the NIBP Simulator.

3.2 System Menu

On the main interface, press the “MENU” button to enter the “SYSTEM MENU” interface. You can perform option operations by using the UP button and DOWN button.

Figure 3.2 Menu System

“ABPM SETUP” in monitoring mode and BP mode is not available, the font is gray, change the

current working mode to ABPM mode to change ABMP settings.

3.2.1 System Settings

Select the “SYSTEM SETUP” item on the “SYSTEM MENU” interface, press the middle button to enter the “SYSTEM SETUP” interface:
“TIME SETUP”: to change the system time
“LANGUAGE”: to change system Language
“DEFAULT” select “YES” in the “DEFAULT” item to restore factory settings
“NEW PATIENT”: after selecting “YES”, the dialog box “Clear the last value?” will appear. Select “YES” again to delete the last recorded patient measurement. Then select “NO” to return to the “SYSTEM SETUP” menu, the monitor does not perform any operations. Please pay attention to this function.
“PROMPT SOUND”: after selecting “ON” in the “PROMPT SOUND” item, the loudspeaker is turned on and the monitoring prompt is executed.  will appear on the main monitoring interface. On the other hand, after selecting “OFF”, the loudspeaker is not activated,  it will appear on the main monitoring interface. When changing the settings, the password input box will pop up, enter the passcode “8015” to change. To enter the passcode: move the cursor in the password display area, press the middle button, when the rectangular frame turns red, to adjust the number with the “UP” and “DOWN” buttons, then press the middle button again to exit the selected section after Settings. After entering the password, move the cursor to “CONFIRM”, then press the middle

button, the prompt setting will change if the password is correct.
“FUNCTION SELECT”: selects between PM, ABPM, and BP modes
“BACKLIGHT TIME(s)”: in ABPM mode, the user will select the backlight time, the range is 5~120 seconds, the adjustment rate is 5 seconds.

3.2.2 BP Settings

Select “BP SETUP” in the “SYSTEM MENU” to enter the sub-menu:
“AUTO MEASURE”: when the user selects “ON” in the “AUTO MEASURE” item, the unit will measure the blood pressure based on the time selected in the “INTERVAL (min)” item, and measurement is also available. When selecting “OFF”, this is manual measurement mode, the item “INTERVAL (min)” becomes gray, which indicates the setting cannot be performed.
“INTERVAL (min)”: 5, 10, 15, 20, 30, 45, 60, 90 minutes.
The prompt is set according to the high and low limit settings, when the pressure is higher than the high limit or lower than the low limit, a prompt will occur. SYS PROMPT and DIA PROMPT will occur over prompt.
Customizable prompt range:
“SYS HIGH”: higher than the lower limit of the prompt systolic pressure, 270 mmHg
“SYS LOW”: lower than the high limit of the prompt systolic pressure, 40 mmHg
“DIA HIGH”: lower than the high limit of the systolic prompt pressure, higher than the low limit of the diastolic prompt pressure.

“DIA LOW”: lower than the high limit of the prompt diastolic pressure, 10 mmHg

3.2.3 SpO2 setting

Select “SpO2 SETUP” on the “SYSTEM MENU” to enter the sub-menu.

Select “ON” on the “PULSE SOUND” item, then there is a ticking sound when SpO2 measurement is taken.

Otherwise, there is no ticking sound.

“SpO2 PROMPT”: based on setting high and low limit, when SpO2 is higher than high limit or lower than low limit, prompt will occur.

“PR PROMPT”: according to setting high and low limit, when PR is higher than high limit or lower than low limit, a prompt will occur.

Customizable prompt range:

“SpO2 HIGH”: higher than the low limit of the SpO2 prompt, 100%

“SpO2 LOW”: lower than the high limit of the SpO2 prompt, 85%

“PR HIGH”: higher than the low limit of the PR prompt, 250 BPM

“PR LOW”: lower than the high limit of the PR prompt, 30 BPM

3. 2.4 ABPM Settings

Select “ABPM SETUP” on the “SYSTEM MENU” to enter the sub-menu shown as follows:

Figure 3.2.4 ABPM Settings

The increment setting for “ASLEEP TIME” and “AWAKE TIME” is 30 minutes, the setting range is 00:00~23:30.

The increment setting for “SPECIAL START” and “SPECIAL END” is 30 minutes, the setting range is 00:00~23:30 and “NONE”.

“ASLEEP INTERVAL”, “AWAKE INTERVAL”, and “SPECIAL INTERVAL”: 5, 10, 15, 45, 60, 90, 120 minutes and NONE. When one of “SPECIAL START” and “SPECIAL END” is set to “NONE”, “SPECIAL INTERVAL” will be cancelled.

3.2.5 BP Table

Select "BP TABLE" on the "SYSTEM MENU" to enter the sub-menu shown as follows:

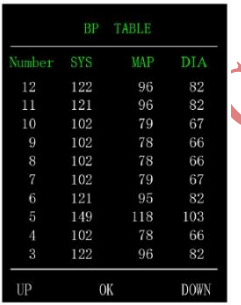


Figure 3.2.5 BP Table

Display the appropriate blood pressure data based on the applicable working mode, press the UP/DOWN button to move the page.

3.4.4 SpO2 Table

Select “SpO2 TABLE” on the “SYSTEM MENU” to enter the sub-menu shown as follows:

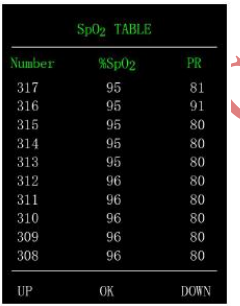


Figure 3.2.6 SpO2 table

Display the appropriate SpO2 data based on the applicable working mode, press the UP/DOWN button to move the page.

3.2.7 DEMO

Select “DEMO” on the “SYSTEM MENU” to enter the sub-menu. In the DEMO interface, press bottom “MENU” to return to the trend chart interface, it is shown like so:

Figure 3.2.7 DEMO Interface

⚠ Notes ⚠

In clinical applications, this function is prohibited because DEMO would mislead medical staff to treat DEMO waveforms and parameters as actual patient data, which could result in treatment delays or incorrect treatment.

Chapter 4 Monitoring SpO2

4.1 What is SpO2 Monitoring

The SpO2 Plethymosgram setting is used to determine the oxygen saturation in hemoglobin in arterial blood. If, for example, 97% of the hemoglobin molecules in red blood cells in arterial blood combine with oxygen, then the blood has an oxygen saturation SpO2 of 97%. Numeric SpO2 on the monitor will read 97%. The numerical SpO2 indicates the percentage of hemoglobin molecules that combine oxygen molecules to form oxyhemoglobin. The SpO2/PLETH parameter will provide a pulse signal and a plethymogram waveform.

How SpO2/PLETH Parameters Work

- **Arterial oxygen saturation is measured by a method called a pulse oximeter. Pulse oximeter is a continuous non-invasive method based on different absorption spectra of reduced hemoglobin and oxyhemoglobin. It measures how much light is sent from a light source on one side of the sensor, then transmitted through the patient's tissue (eg finger or ear), to receive on the other side.**
- **The amount of light transmitted depends on many factors, most of which are constant. However, one of the factors, the absorption of light during pulsation, allows to obtain the oxygen saturation of the arterial blood. Detecting pulsations provides a PLETH**

waveform and pulse signal.

- **SpO2 value and PLETH waveform can be displayed on the main display.**
- **Please read the measurement value when the bubbling on the screen is stable. The measurement value is the optimal value. And swell at the moment on a standard.**

Optical Sensor: Red light (wavelength about 660nm, optical power output less than 6.65mW), infrared light (wavelength about 880nm, optical power output less than 6.75mW). Optical sensors are included in light-emitting components, which will cause interference with other medical equipment with a wide range of wavelengths. This information will be useful for doctors for optical treatment.

⚠ **Notes** ⚠

- **Patient Monitor using integrated SpO2 probe (measurement section integrated with probe)**
- **The lifetime of the integrated SpO2 is 3 years.**

⚠ **Warning** ⚠

ES (Electrosurgery) cable equipment and SpO2 cables must not be tangled.

⚠ **Warning** ⚠

Do not place the sensor on an extremity with an arterial catheter or venous syringe.

⚠ **Notes** ⚠

Do not take the SpO2 measurement and the NIBP measurement on the same arm at the same time, as blockage of blood flow during the NIBP measurement can affect the SpO2 reading.

4.2.1 Warning when Monitoring SpO2/Pulse Rate

⚠ **Notes** ⚠

- Make sure the nails cover the light. The probe cable should be on the back of the hand. Improper installation of the probe or improper contact with the test part will affect the measurement results.
- SpO2 values are always displayed in a fixed place.
- The testing department must not use external coloring agents (such as nail polish, dyes or colored skin care products, etc.), otherwise it will affect the measurement.
- Fingers that are too cold or too small will affect the accuracy of the measurement, please use a thicker finger such as your thumb or middle finger deeper into the probe.
- The SpO2 probe is suitable for children and adults (not suitable for infants and newborns). Units are not suitable for all patients. If unable to achieve a stable reading, discontinue use.
- Data averaging and signal processing will delay the appearance of data and SpO2 values.

The measurement data update time is less than 30 seconds, when the signal attenuation, weak perfusion or other interference appears, it will result in an increase in the dynamic data average time depending on the PR value.

- The PLETH waveform is not normalized, which is used as an indicator of signal incompleteness. So, the accuracy of the measured value may decrease when the waveform tends to be not smooth and stable. When the waveform tends to be smooth and stable, the reading is the optimal value, and the current waveform is the most standard.
- The temperature for the contact surface of the device with the body is less than 41 °C, and this temperature value is measured by a temperature measuring device.
- The device does not provide an alarm function that exceeds the limit, so it cannot be used where the function is required.
- The SpO2 probe is calibrated before it leaves the factory. No need to calibrate during maintenance.
- The SpO2 probe is calibrated to show functional oxygen saturation.
- The SpO2 probe and photoelectric receiving tube should be arranged so that the subject's arterioles are positioned in between. Make sure the optical path is free of optical obstructions such as rubber cloth, to avoid inaccurate measurements.
- Since measurements are based on arteriolar pulses, substantial pulsed blood flow from the subject is required. For subjects with a weak pulse due to shock, low ambient/body temperature, heavy bleeding, or use of vascular contracting drugs, the SpO2 (PLETH)

waveform will decrease. In this case, the measurement will be more sensitive to interference.

- The accuracy of the readings under weak perfusion was verified using signals from the patient simulator. SpO2 and pulse rate values vary within the measurement range due to various weak signal conditions and are compared with the actual SpO2 and pulse rate values of the known input signal.
- Claims of SpO2 accuracy must be supported by clinical research measurements spanning the entire spectrum. By artificially inducing different stable oxygen levels, keep them in the 70~100% range. Use secondary standard SpO2 measuring equipment for comparison to collect SpO2 values along with the product being tested, create paired data sets for accuracy analysis.
- The clinical report recorded data on 12 healthy volunteers, including 6 women and 6 men. The age of the volunteers ranged from 21 to 29 years. Skin color is distributed from dark to light, including 3 dark skin, 2 medium black, 5 light skin, 2 white skin.
- When using the device, keep it away from instruments that can generate strong electric or magnetic fields. Using the device in an unsuitable environment may cause interference to nearby radio equipment or affect its operation.
- If necessary, please go to our company's official website to download the list of Sp02 probes and extension cables that can be used with this device.

⚠ Warning⚠

- Check if the Sp02 probe cable is in normal condition before measuring. After unplugging the Sp02 probe from the socket, the "Sp02%" and "bmp" on the screen will disappear.
- Do not use the Sp02 probe once the package or probe is found to be damaged. Instead, you must return it to the vendor.
- The included Sp02 probe is only suitable for use with this device. This device can only use the Sp02 probe described in this manual. It is the operator's responsibility to check the compatibility of the Sp02 device and probe (and extension cord) prior to use. Incompatible accessories may result in decreased device performance or cause injury to the patient.
- Sp02 probe is a medical product that can be used repeatedly.
- The measured values may appear normal in the testee who has anemia or hemoglobin dysfunction (such as carboxyhaemoglobin (COHb), methaemoglobin (MetHb) and sulfhaemoglobin SuHb)), but the testee may appear hypoxic, it is advisable to carry out further assessment according to the situation and clinical symptoms.
- Pulse oxygen has only reference significance for anemia and toxic hypoxia, because some patients with severe anemia still show better pulse oxygen measurements.
- Measurement accuracy may be affected by interference with electrosurgery equipment.
- Do not attach the Sp02 probe to an extremity with an arterial catheter or receive intravenous injection.

- Do not take the Sp02 measurement and the NIBP measurement on the same limb at the same time, because blockage of blood flow during the NIBP measurement can affect the Sp02 value reading.
- Excessive movement (active or passive) of the subject or strenuous activity can affect measurement accuracy.
- Excessive ambient light can affect the measurement results, such as surgical light (especially xenon light source), bilirubin lamp, fluorescent lamp, infrared heater and direct sunlight, etc. To prevent interference from ambient light, be sure to position the probe properly and cover the probe with an opaque material.
- The measured values may not be accurate during defibrillation and for a short time after defibrillation, because the Sp02 probe does not have a defibrillation hold function. with opaque materials.
- The measured values may not be accurate during defibrillation and for a short time after defibrillation, because the Sp02 probe does not have a defibrillation hold function.
- People who are allergic to silicone, PVC, TPU, TPE or ABS cannot use this device.
- For some special patients, the examination should be more careful in the measurement section. The probe cannot be cut in edema and soft tissue.
- Do not look directly at the luminescent components when the device is turned on (infrared light is not visible), even for maintenance purposes, or it may be bad for the eyes.
- Feelings of discomfort or pain may occur with continuous use of the Sp02 probe, especially

for patients with microcirculation barriers. It is recommended that measurements are not taken in the same position for more than 2 hours. Continuous and prolonged measurement can increase the risk of undesirable changes in skin characteristics, such as extreme sensitivity, redness, blistering or pressing necrosis, especially for neonates or patients with impaired perfusion and changes or immature skin shape. Particular attention should be paid to checking the position of the probe placement according to changes in skin quality, correct optical alignment, and method of insertion. Check the attachment position periodically and change it as the leather quality deteriorates. More frequent examinations may be required due to differences in the patient's condition.

- Some functional test models or patient simulators can measure the accuracy of devices that reproduce calibration curves, but cannot be used to evaluate the accuracy of these devices.
- please refer to the relevant medical literature for detailed clinical limitations and contraindications,
- This device is not used for medicinal purposes.
- Do not use the SpO2 probe during MRI and CT scans, as the induced current can cause burns.
- When the device is ON, if the power is cut off for more than 30 seconds, the SpO2 probe does not require operation after the power is restored, after the device is turned on, make sure the SpO2 probe can be used normally.
- The probe can be used before/after exercise, but is not recommended for use during exercise.

4.2 Monitoring Procedure

⚠ Notes ⚠

SpO2 display range: 0 ~ 99 %, PR display range: 30 bpm (beats/min) ~ 250 bpm (beats/min).
If the SpO2 is working abnormally, after connecting the SpO2 probe to the device, the device will not display any data under the SpO2 interface.
SpO2. plethysmogram measurement
1. Turn on the patient monitor.
2. Attach the sensor to the right place of the patient's finger.
3. Plug the sensor extension cable connector into the SpO2 socket, please pay attention to the direction of the socket connection.
4. Please pull it out of the sensor when the measurement is finished.

Figure 4.3 Sensor Installation

Measurement Limit

During operation, the accuracy of SpO2 readings may be affected by:

- High frequency electromagnetic interference such as interference from electrosurgery equipment connected to the system.
- Intravenous dye.
- Excessive patient movement.
- External light.
- Incorrect installation of the SpO2 probe or wrong patient contact position.
- SpO2 probe temperature (optimal temperature range: 28°C
- Place the Sp02 probe on the extremity that has a blood pressure cuff, arterial catheter, or intravascular line
- Dysfunctional hemoglobin concentrations, such as carboxyhemoglobin (COHb) and methemoglobin (MetHb).
- Sp02 is too low, circumferential perfusion is poor in the measured part.
- Intravascular dyes (such as indocyanine green or methylene blue), skin pigmentation.
- It is necessary to use the Sp02 probe provided by our company, contact our sales department when needed.

Chapter 5 NIBP Monitoring

5.1 Introduction

- **The Non-invasive Blood Pressure Module (NIBP) measures blood pressure using the oscillometric method. Namely: using a blade to block arterial blood, checking the oscillometric waveform during degassing to ensure that it is not affected by operator subjective factors or environmental noise interference.**
- **There are two measurement modes available: manual and automatic. Each mode displays diastolic, systolic and MAP blood pressure and pulse.**

❖ **"Manual" mode: Only one measurement is taken at a time.**

❖ **"Auto" mode: Measurement starts automatically the device reaches the automatic measuring point.**

⚠ Warning⚠

Prolonged non-invasive blood pressure measurement in Auto mode can be associated with purport, ischemia, and neuropathy in the cuff-wearing extremity. While monitoring the patient, check the extremities of the extremities frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop measuring blood pressure.

⚠ Warning⚠

You should not take NIBP measurements on patients with sickle cell disease or in any condition whose skin is damaged or expected to be damaged.

For thrombasthemic patients, it is important to determine whether blood pressure measurements should be automated. Determination should be based on clinical evaluation.

5.1 Monitoring NIBP

⚠ Notes ⚠

- Do not talk or move during measurement.
- Do not use a mobile device such as a cell phone near the device when measuring.
- The measurement results may differ due to different cuff positions.
- Do not touch the device, cuff or extension tube during measurement.
- See Safety Precautions for contraindications to NIBP measurements.
- Please use the device under proper temperature and humidity (see related chapter), otherwise the measurement result may not be accurate.

⚠ Warning⚠

The minimum value for the patient's physiological signal is the lower limit that the device

can measure. Measurement results may not be accurate if the device is running below the minimum amplitude or minimum value of the patient's physiological signal.

Prolonged non-invasive blood pressure measurement can be associated with purpura, ischemia, and nerve injury to the cuff-wearing extremity. When monitoring the patient, check the color, warmth and sensitivity of the distal limb as often as possible. If any abnormality is observed, stop measuring immediately or change the location of the cuff.

Do not twist or kink the airway tube, otherwise it will cause continuous pressure on the cuff, then cause blockage of blood flow and serious injury to the patient.

Do not use the cuff on the injured area, otherwise it will cause more serious damage to the injured area.

Do not use the cuff where intravascular treatment is being performed or with a catheter connection, otherwise it may cause a temporary blockage of blood flow and subsequently cause injury to the patient.

Do not use the cuff on the mastectomy side;

Pressure with the cuff can cause temporary weakness of some body functions.

So do not use medical electrical monitoring equipment in the appropriate arm.

Do not move during the measurement, as this will affect the patient's blood flow.

Do not move during the measurement, as this will affect the patient's blood flow.

The device requires a recovery time of 2 hours to reach its intended use performance after being removed from the lowest storage temperature.

The device requires a recovery time of 4 hours to reach its intended use performance after being removed from the highest storage temperature.

1. Plug the air hose into the cuff socket on the device, and connect the device to a power source.
2. Place the cuff on the patient's upper arm following the instructions below.

- Make sure the cuff is completely deflated.
- Place a cuff of the appropriate size on the patient, and ensure that the "φ" symbol is above the appropriate artery. Make sure the cuff is not wrapped too tightly around the limb. Cuffs that are too tight can cause discoloration and eventually ischemia of the extremities.
- Make sure the edge of the cuff is within the range of the <-> mark. Otherwise, use a larger or smaller cuff that fits better.

Figure 5.2 Installation of the cuff

3. Connect the cuff to the air hose. The cuff should be placed at the same level as the patient's heart.

If not, modify the measurement results with the following methods:

- If the cuff is placed higher than heart level, add 0.75 mm Hg (0.10 kPa) for every inch of difference.
- If placed lower than heart level, minus 0.75 mmHg (0.10 kPa) for every inch of difference.

4. Press the NIBP button on the front to start pumping and measuring.

Measurement Limit

The oscillometric method has some limitations depending on the patient's condition. This measurement is based on a regular pulse wave generated by arterial pressure. In cases where the patient's condition makes such a method of detection difficult, the measured values become unreliable and the measurement time increases. The user should be aware that the following conditions will make the measurement unreliable or the measurement time extended. In this case, the patient's condition will make measurement impossible:

- Patient Movement

Measurements will be unreliable or unreliable if the patient is moving, shivering or having seizures. This movement can interfere with pulse detection of arterial pressure. In addition, the measurement time will be extended.

- Heart arrhythmia

Measurements are not reliable and may not be possible if the patient's cardiac arrhythmia has

caused an irregular heartbeat. Thus, the measurement time will be extended.

- *heart-lung* machine

Measurement will not be possible if the patient is connected to a *heart-lung machine*.

- Pressure Change

Measurements will be unreliable and impossible if the patient's blood pressure changes rapidly over a period of time during which the arterial pressure pulse is analyzed to obtain the measurement.

- Severe shock

If the patient is in severe shock or hypothermia, measurement is not reliable because reduced peripheral blood flow will result in reduced arterial pulse.

- Extreme Heartbeat

Measurements cannot be taken at heart rates less than 40 bpm and greater than 240 bpm.

- Obese patient

A thick layer of body fat will reduce measurement accuracy, because fat originating from arterial shock cannot access the cuff due to damping.

The following conditions can also cause changes in blood pressure measurement values:

- After eating (within 1 hour), or drinking alcohol or caffeine, or after smoking, exercising or bathing;

- Using wrong postures such as standing or lying down, etc.;
- The patient speaks or moves his body during the measurement;
- When measuring, the patient is nervous, excited, or emotionally unstable;
- The room temperature rises or falls drastically, or the measurement environment changes frequently;
- Measuring in a moving vehicle;
- Position of cuff attached (higher or lower than heart level);

5.3 NIBP Error Messages and Solutions

Error Message	Meaning	Because
00	No error	
02	Self test failure	Possible sensor error or A/D sampling
03	No error	
04	Low battery	Battery voltage is low
05	Cancel measurement	Measurement cancelled
06	Remove Cuff	Cuff not connected, or too loose
07	Air leak	Air leaks in valves or air ducts.
08	Atmospheric pressure error	The valve cannot be opened.

09	Weak signal	The pulse of the measured subject is too weak or the cuff is loose.
10	Out of range	The measured subject's NIBP value exceeds the measurement range.
11	Excessive movement	Movement may cause too much interference to the signal during the measurement process.
12	Excessive pressure	If the cuff pressure is out of range, the cuff may be blocked or extruded.
13	Saturated signal	Movement or other factors can cause the signal amplitude to be too large.
14	Air leak	System air duct leak found in leak detection.
15	System failure	Possible failure caused by pump, A/D sampling, pressure sensor error, or software operating error.
19	Time has run out	Measurement time longer

		than specified, adults and children: 150 seconds, neonates: 90 seconds
--	Error display	Check if the battery is installed properly.

Chapter 6 Maintenance and Cleaning

***Please observe the precautions and correct operating methods in this Manual. Otherwise, we will not be responsible for any errors.**

⚠ Warning⚠

- Remove the battery before cleaning the device or peripheral equipment. Accessories and main unit must be separated for cleaning.
- Do not press the rubber tube against the cuff.

Cleaning:

- Do not immerse the device and accessories in liquid.
- If you find damage or loss of performance of your device and accessories, do not reuse them.
- Do not allow water or cleaning agents to run into the socket to avoid damaging the device.
- Do not use gasoline, essential oils, thinners, etc. to wipe the device.

Maintenance:

- Clean the device and accessories regularly. It is recommended to clean it every month. When dirty, use a dry, soft cloth to wipe. If the device, accessory or peripheral equipment is very dirty, it is recommended to dip a soft cloth in water or a mild detergent, and wring it out, then use the cloth to clean. Don't clean the inside.

■ Devices should be checked and calibrated periodically (or comply with hospital requirements). Units can be inspected at state-specified inspection bodies or by private professionals, or you can contact our company.

Reusable Blood Pressure Cuff

Cufflinks can be sterilized by conventional autoclaving, gas, or radiation sterilization in a hot air oven or disinfected by immersion in a decontamination solution, but remember to remove the rubber bag if you use this method. Cufflinks should not be dry washed. It can be machine washed or hand washed, the latter method can prolong the life of the cuff. Before washing, remove the latex rubber bag. Allow the cuff to dry completely after washing, then reinsert the rubber bag into the cuff.

Figure 6 .1 Replace the rubber bag

To insert the rubber bag into the cuff, first place the bag over the cuff so that the rubber tube is

aligned with the large hole on the long side of the cuff. Now roll the bag lengthwise and insert it into the hole on the long side of the cuff. Grasp the hose and cuff and wiggle the cuff until the bag is in position. Insert the rubber tube from inside the cuff, and out through the small hole under the inner cover.

Disposable Blood Pressure Cuff

Disposable cuffs are intended for single patient use only. Do not use the same cuff on another patient. There is no disinfection or sterilization of high-pressure steam to single-use cuffs. Disposable cuffs can be cleaned using a soap solution to prevent infection.

Notes

Considering environmental protection, disposable blood pressure cuffs should be recycled or disposed of properly.

Storage:

Suggestion

- Do not expose the device to direct sunlight for a long time, otherwise the screen display may be damaged.
- The basic performance and safety of the device is not affected by dust or cotton in the home environment, while the device must not be placed in a place with high

temperature, humidity, dusty or corrosive gases.

- Old cufflinks may cause inaccurate measurements, please replace the cuff periodically according to the user manual.
- To avoid damage to the device, keep the device out of reach of children and pets.
- Avoid devices that are close to extreme high temperatures such as fireplaces, otherwise the performance of the device may be affected.
- Do not store the device with chemicals or corrosive gases.
- Do not place the device where there is water.
- Do not place the device where it is subject to tilt, vibration, or impact

Chapter 7 Software Installation

Processor: Base frequency 2.5G or more

Operating System: Windows XP or higher version

EMS memory: 1GB or more

Hard Disk: 250G or more

Display: Resolution ratio 1024*768 or more

USB: 2 or more

Printer resolution: 600 DPI

Chapter 8 Software Introduction

8.1 Patient Registration

Double click on the software icon, a dialog box like the following will appear

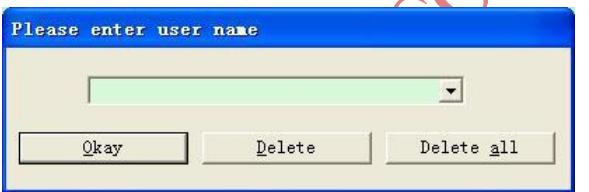


Figure 8.1.1 User Registration

Enter the user name, click “Okay” then the “Configuration Set” dialog box will appear as shown in Figure 8.1.2. Click “Delete” to delete the user configuration information. “Delete all” is used to delete the configuration information of all users. If you are a new user, the following dialog box will appear.

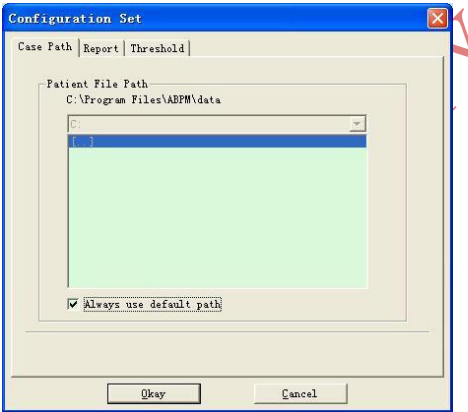


Figure 8.1.2 Configuration Settings

“Case path”: select the default save location for the examination, after getting data from the tool, the examination file will be saved in this location.

If you select "Always use default path". Then the inspection file will be saved automatically at

the installation location.

8.2 Main Interface

The unit will enter the main interface (shown as shown below) after setting the configuration information.

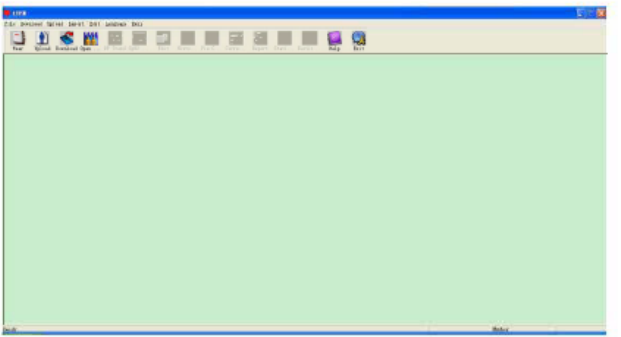


Figure 8.2 Main Operation Interface

8.3 Usage

After pressing the hotkey an 

, the following image will appear. Before using the tool, please read the “Matters need” carefully, and use the tool according to the following picture.

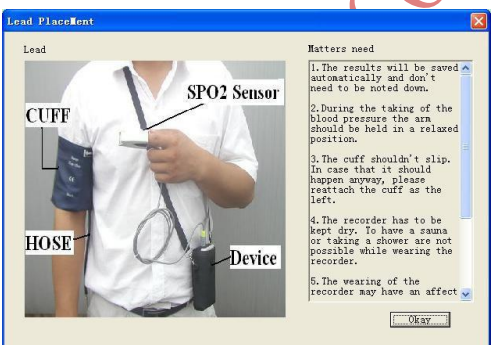


Figure 8.3 Usage

8.4 Settings Collection Plan

Click the shortcut key 

, or click the menu image “Upload”, from the menu, after selecting the connection mode, the “Select the status of the device” dialog box will appear.:

Figure 8.4.1 *Select the Device Status*

If you select “ABPM”, a dialog box like the following will appear.

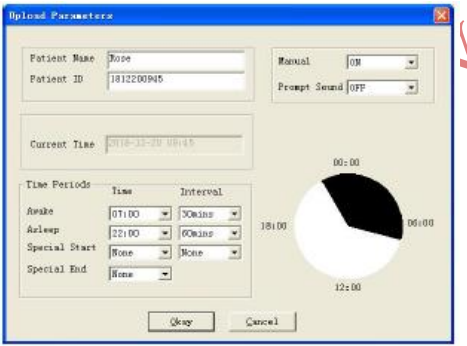


Figure 8.4.2 Establish a Collection Plan

As the picture above, the doctor can set the parameters according to the patient's status and diagnosis needs, then the monitor can complete the collection according to the settings. Parameter explanation is as follows:

Patient Name: patient name

Patient ID: patient ID number. Used to mark patients, and this is exclusive to avoid homonymous patient states

Current Time: Current system display time
Start Key: whether support to collect by manual operation.
Parameter setting for Time Period:
Awake: time to wake up
Asleep: time to go to sleep
Special and Special End: optional items, they are used to set the data collection plan in a special time. Interval: the acquisition time interval, taking into account the effect of minimizing the impact on the patient's sleep, the interval during sleep is generally set to be longer.
Take the picture above as an example, Awake time zone is 7:00-22:00, Asleep time zone is 22:00 -7:00 the next day. "Interval" in " Awake " is 5 minutes, "Interval" in " Asleep " is 30 minutes. Asleep time zone, Awake time zone, custom measurement time zone will be displayed at bottom right in graphic form, which is suitable for parameter setting.
"PROMPT SOUND": after selecting "ON" in the "PROMPT SOUND" item, the loudspeaker is turned on and quick monitoring is performed. On the other hand, after selecting "OFF", the loudspeaker is turned off.
If you select "Patient Monitor", the following dialog box will appear.

Figure 8.4.3 Setting Parameters

Parameter descriptions are as follows:

Patient Name: patient name

Patient ID: patient ID number, used to identify the patient, is unique.

Current Time: the time displayed on the computer, used to update the system time of the device. After setting, click "OK" to set this plan to the device.

"Prompt Sound": after selecting "ON" in the "Prompt Sound" item, the loudspeaker is turned on and quick monitoring is performed. On the other hand, after selecting "OFF", the loudspeaker is turned off.

8.5 Data Download

Before downloading data, please make sure:

1.properly connected to the computer .

2. The monitor is on .

3.Make sure the monitor is not connected to the patient while the monitor is connected to the computer.

The downloaded patient data will be saved if the storage path is set. If you want to change the storage path, select “Set file path”, then a dialog box (Figure 6.1.2) will appear, you can change the path.

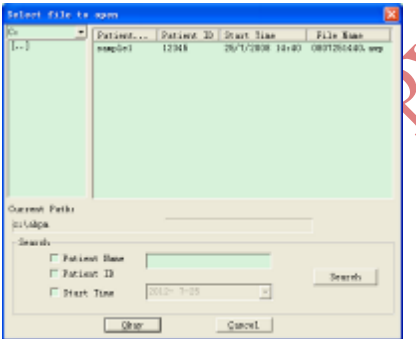
Click the shortcut key 

or menu item " Download ", then select the connection method.

Once connected properly, start downloading data.

8.6 Opening Data Files

Click "open data" to enter look like the following picture



Picture 8.6 Select examination

In this view, you can operate the driver and folder selection at the top left to load the disk and folder contents, if the examination file is in this folder, the basic information of the examination file will be displayed in the form of a list, the contents include: Patient name, patient ID, start time and file name. Click to select the examination file to be opened and then press “Okay” to open and load the examination file information.

If there is a lot of collation data, select a query item, enter key information, then press “Search” to query.

8.7 Data Deletion

If you believe that some data is not needed, you can delete it. Click the " Delete data" menu *item* from the menu to enter the submenu which will look like the following

Figure 8.7 Deleting Data Files

Multiple files can be deleted at the same time. Press the " Ctrl " key, at the same time click *the file* to be deleted. click "OK" to delete the selected inspection file. Press “Cancel” to cancel the deletion.

8.8 Data File Backup

The software has a function for backing up inspection data. Select the "Copy data" menu item, and the interface will appear as follows:

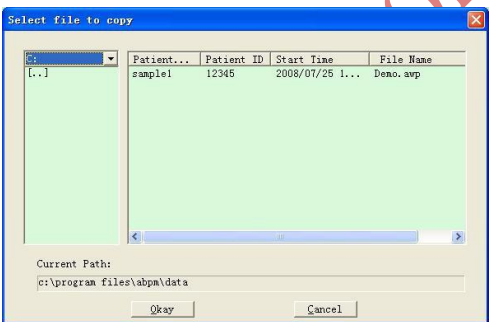


Figure 8.8.1 Copying Data Files

After selecting *the file*, click "Ok vv " then the dialog box used to set the save file of the backup file will appear. Once set, click “Okay” to save. The destination directory display will be shown as follows.

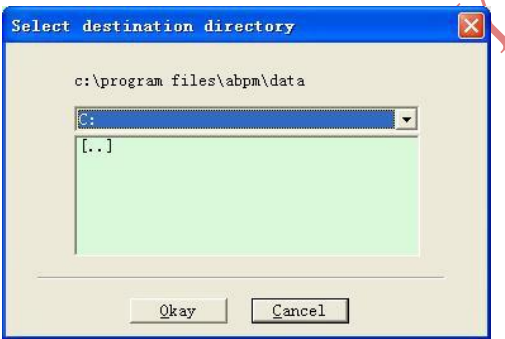


Figure 8.8.2 Backup Path Settings

8.9 Editing BP Data

After opening the inspection file, you can edit each piece of data. Click the shortcut key  or

select the "Edit" menu item to display the "BP Data" interface as follows:

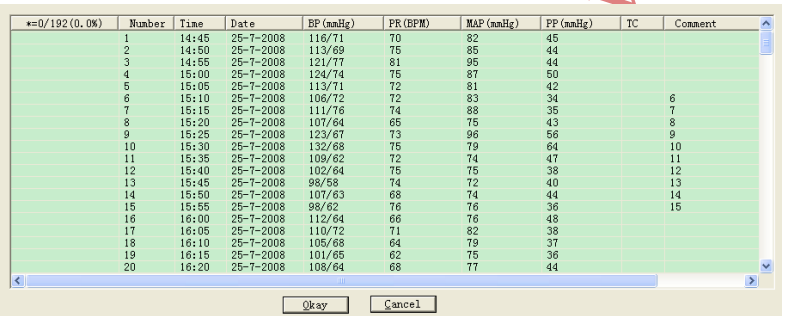


Figure 6.9.1 BP Date Edit Interface

In the interface, you can see the specific information of each data.

*=5/192(2.6%): 192 is the total number of data, 5 is the number of deleted data, 2.6% is the percentage of deleted data.

Number : data collection serial number

Time : collection time

Date : data collection

BP (mmHg): the number in front of "/" is the high pressure value, and the number behind "/" is the low pressure value. The unit is mmHg.
PR (BPM): pulse rate. The unit is BPM.
MAP (mmHg): Average pressure. The unit is BPM
PP (mmHg): Pressure difference between systolic and diastolic pressure. The unit is mmHg
SpO2(%): oxygen saturation, unit is %
TC: error code (see chapter 5)
Comment : comments for data.
This data can also be performed exception operations. The symbol "*" indicates to delete data (not shown in trend charts, and not recorded in statistics). You can click the location area of the first column to be added or removed"*". And in the comments field, you can annotate the data, and the comment information will be displayed in trend charts and reports.

8.10 Edit Trend Chart

8.10.1 BP Trend Chart

After selecting the data file, the BP trend chart will be displayed on the screen automatically. You can click the shortcut key 

to enter the BP trending interface. There are two types of charts: color fill type, dotted line type. The trend chart is shown as below:

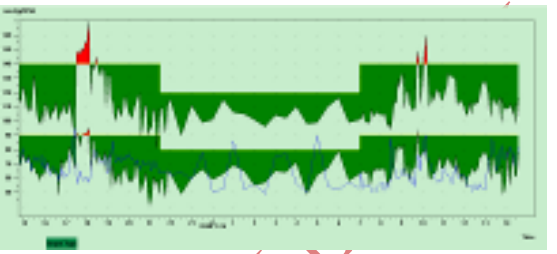
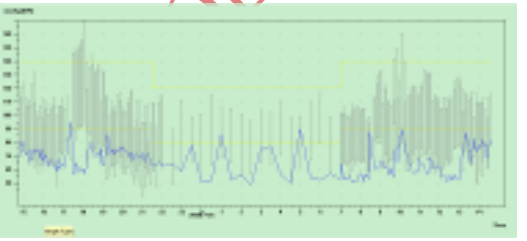


Figure 8.10.1 Trend Graph BP *color filler*



8.10.2 Dotted Line Type BP Trend Chart

You can switch between two types of trend charts with the "Chart Type" button at the bottom of the software interface. As you move your mouse over the trending area, detailed data information on this location will be displayed at the top of the footprint area, including data serial number, collection time and date of collection, high/low blood pressure values, pulse rate, comments, etc. Press the left mouse button1 to delete or add a data point to be displayed.

8.10.2 SpO2 Trend Chart

When you open the case file with Sp02 data, click "Sp02 Trend" to enter the Sp02 trend interface.

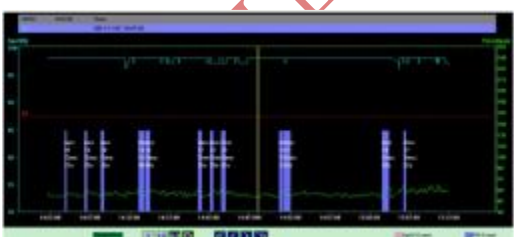


Figure 8.10.3 SpO2 . Trend Graph

4 buttons 

used to set the length of time for a single page, i.e. how long the data will be visible at the same time in the window area from left to right.

the current screen displays an I-minute trend chart.

the current screen displays a 10-minute trend chart.

the current screen displays an I-hourly trend chart.


a dialog box will appear after pressing this button, then you can set the length of time according to your need.

4 buttons 
are used to move the trend backwards or forwards. Select “Set Parameters” to enter the sub-menu shown as follows.

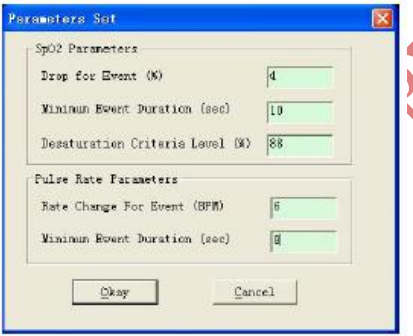


Figure 8.10.4 Parameter Analysis Settings

The settings in the dialog box above show:

SpO2 occurrence (wish): SpO2 value decreased by at least 4%, which is continuous time of at least 10 seconds.

Pulse Pulse Event: pulse rate fluctuates at least 6bpm, which is a continuous time of at least 8 seconds.

8.11 Display of Statistical Information.

Press the shortcut 

or select "Report" from the menu to enter the sub-menu as below.

Figure 8.11 BP Statistical Information

The top half of the image shows the average of the blood pressure data and measurement numbers

under the " Awake" and "Asleep" states. The lower part shows the percentage of warning value data, 140/90, 120/80 represents the blood pressure warning value of systolic and diastolic pressure under "Awake" and "Asleep" states, the unit is mmHg.

8.12 Edit Diagnostic Information.

Select "Patient Data" from the menu to enter the sub-menu shown as below. Patient information including: patient information, current medication, diagoose information and doctor information.

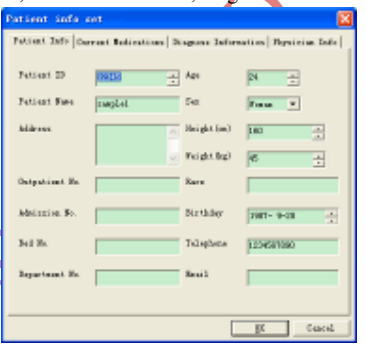


Figure 6.11.1 Edit Patient Information

The latest patient medication information can be entered in the "Current Medication" column. A description of the blood pressure data and diagnostic information can be entered in the "Diagnose Information" column.
The doctor's name and doctor's advice can be entered in the "Physician Info" column.

8.13 Sleep Timing

Wake up and sleep time can be set by manual mode after setting, software will calculate data again under "Awake" and "Asleep" status, then update trend chart and calculate statistical data automatically. The interface shown as below will appear after selecting "Sleep Period" from the menu.

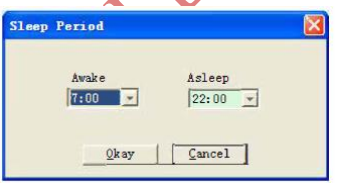


Figure 8.13 Sleep Timing

8.14 Set BP Threshold

The BP threshold can be changed by manual mode, once it changes, the trend chart and the corresponding analysis data will be updated automatically. Select "Threshold" to enter the sub-menu shown as below.

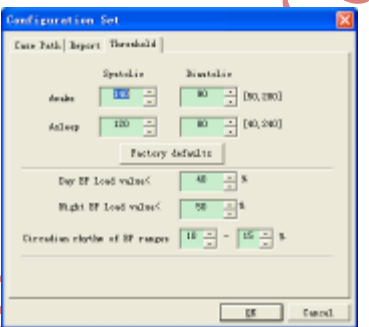


Figure 8.14 Set BP Threshold

The recommended default thresholds for calculating the Blood Pressure Load are 140/90 for waking periods and 120/80 for sleep periods. This is the default value when you select the Factory

Default button.

8.15 Histogram

Click the hotkey  , and the following interface will appear.

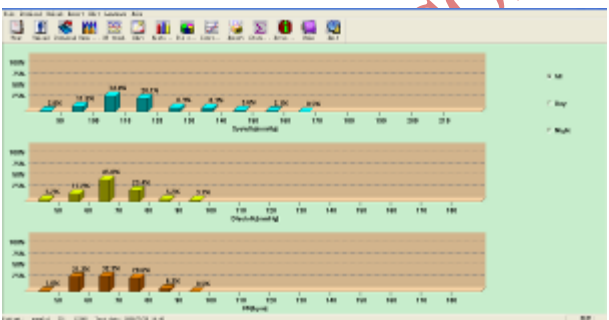


Figure 8.15 Histogram

" All ", " Day " and " Night " each can display the analysis value in each period.

8.16 Pie Charts

Click the hotkey  , and the following interface will appear.

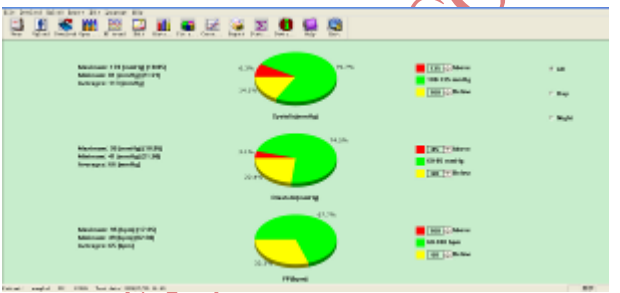


Figure 8.16 Pie Chart

The pie chart interface is divided into four regions, from left to right, the first region is the value display area which displays the Maximum, Minimum and Average values among the measurement values, the second region is the pie chart display area, the third is the setting area for color and pie chart values, and finally the time display area, has three options: " All", "Day" and "Night", each

of which can display analysis values in each period.

8.17 Correlation Line

Click the hotkey 

, and the following interface will appear.

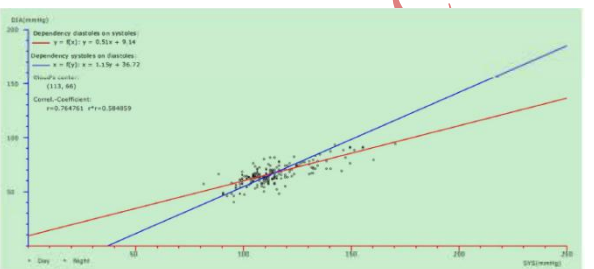


Figure 8.17 Correlation Line

The horizontal axis is the systolic pressure axis, and the vertical axis is the diastolic pressure axis. Red represents the dependence of diastolic pressure on systolic pressure; blue represents the dependence of the systolic pressure on the diastolic pressure. The hollow circle is the BP value

measured during the day, and the solid circle is the BP value measured at night.

8.18 Print Report

After editing BP data and diagnosis information, click "Report", the software will generate a series of diagnosis reports, you can select all pages or some of them to print.

Select "Configure Report" in "Report", then the following image will appear.

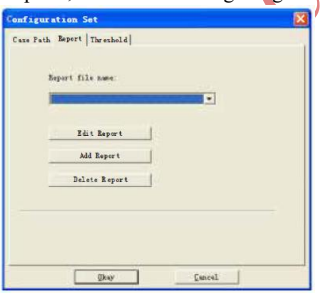


Figure 8.18.1 Report Configuration

You can select a configured report for printing, or click "Edit Report" to edit the selected report.

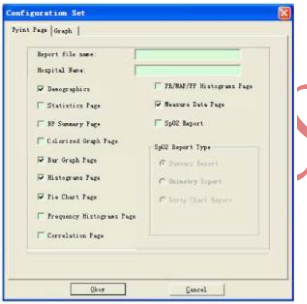


Figure 8.18.2 Edit Report

The Sp02 analysis report can only be printed when the case file contains Sp02 and "Sp02" report " is selected. Click " Add Report " to add a new report. If you don't need the current report, you can also click " Delete Report " to delete it .

Click the shortcut key 

or select “Report” from the menu to preview the report, then select “Print” to print the report.

8.19 Help

Click the shortcut key 

to its sub-menu, which provides a brief description of each program function. In addition, you will find the "Help" button in each operating interface, click it to check the description of this function, which makes it easy for you to quickly find out how to use the software.

Chapter 9 Symbols

Signal	Description	Signal	Description

	Attention! Please refer to the accompanying document (user manual)		Attention! Please refer to the accompanying documents (the user manually).
SYS	systolic pressure	HE	diastolic pressure
FOLDER	Average blood pressure	PR	Pulse rate (bpm)
SpO2	Functional arterial oxygen saturation	EMC	Electromagnetic compatibility
IPXX	Degree of protection against splashing water	P/N	Manufacturer material code
ADU	Mature	NEO	Neonatal
ABPM	Ambulatory Blood Pressure Monitor	PM	Patient Monitor Mode
PED	Pediatric	INFO	Information
SN	Serial Number		Recyclable
	Silence		Class II equipment
	Voice indication message off		Voice indication message on
LOT	lot code		Date of initial use

	This side is facing up		Vulnerable, handle with care
	Store in dry place		Storage atmospheric pressure limit
	Storage temperature limit		Storage humidity limit
	Manufacturer		Production date
	Battery power		Pulse rate (bpm)
	1. No finger enters the SpO2 probe 2. No NIBP review data 3. Insufficient signal indicator		1. No pulse rate 2. Insufficient signal indicator
	Waste disposal sign, this symbol indicates that electrical waste and electrical equipment cannot be		Unit complies with Medical Device Directive 93/42/EEC

	disposed of as general unclassified waste and must be recycled separately	CE 0123	June 14, 1993, directive of the European Economic Community
EC REP	European Representative		Defibrillation resistant BF type
	Natural latex free		

Chapter 10 Specifications

Name	Patient Monitor
Degree of protection against water ingress	IPX1
Display	2.4" color LCD screen
Operation mode	Continuous
NIBP Specification	
Measurement Method	Oscillometric method
working mode	Automatic
Blood pressure	
Measurement Range	Pressure: 0~284 mmHg (0~37.9 kPa)
Cuff Pressure Accuracy	Static Pressure: ±3 mmHg (±0.4 kPa)
Over Pressure Protection	Adult: 284 ±3mmHg (37.9±0.4 kPa)
Pre-inflation Value	Adults: 160 mmHg (21.33 kPa)
Resolution	1 mmHg (0.133 kPa)
Failure	The BP value measured by the device is equivalent to the Stethoscope measurement value, carry out clinical verification according to the requirements in ISO 81060-2:2013, the error

	meets the following: Maximum mean error: ±5 mmHg Maximum standard deviation: 8 mmHg
SpO2	
Measurement Range	0~99%
Resolution	1%
Failure	The measured value is in the range of 50%~99%, the absolute error is ±2%, below 0~49% is not determined.
Measurement Performance in Weak Charge Condition:	SpO2 and pulse rate can be displayed correctly when pulse fill ratio is 0.4%, SpO2 error is ±4%; pulse rate error is ±2 bpm or ±2%, whichever is greater
Pulse	
Measurement Range	30~250 bpm
Resolution	1 bpm
Accuracy	±3 bpm or 2% (whichever is greater)
Operating temperature/humidity	+5ºC ~ 40ºC ≤85 %RH (Non-condensing)
Transport	Transportation by public transportation or according to the contract order, avoid bumping, shaking and splashing by rain and

	snow in transportation.
Storage	Temperature: -20ºC ~ +60ºC; Relative humidity: ≤95%; No corrosive and windy gas.
Atmospheric pressure	Working: 700hPa-1060hPa Transport and Storage: 500hPa-1060hPa
Power supply	DC 3V
Battery life	When the temperature is 23 °C, the leg circumference is 270 mm, the measured blood pressure is normal, 2 "AA" batteries can be used about 150 times.
Rated power	≤3.0 VA
Size	137(L)*69(P)*30mm(H)
Unit weight	236 grams (without battery)
Safety Classification	Internal powered equipment Defibrillation-resistant BF type applied par
Lifetime	The life of the device is five years or 10,000 times the BP measurement.
Manufacturer date	See the label

Appendix

Manufacturer's guidelines and declarations – electromagnetic emissions – for all equipment and systems

Manufacturer's guidelines and declarations – electromagnetic emissions		
This device is intended for use in the following electromagnetic environments. The customer using the tool must ensure that the tool is used in that environment.		
Emission test	**Suitability**	**Electromagnetic environment - guide**
RF emissions CISPR II	Group I	This device uses RF energy for internal functions only. Therefore, the RF emission is very low and there is a low probability of causing interference to nearby electronic equipment.
RF emission CISPR II	Class B	This device is suitable for use in buildings other than domestic buildings and networks that are directly connected to low-voltage power sources that supply buildings for domestic purposes.

Manufacturer's guidelines and declarations – electromagnetic immunity – for all equipment and systems

Manufacturer's guidelines and declarations – electromagnetic immunity			
This device is intended for use in the following electromagnetic environments. The customer using the tool must ensure that the tool is used in that environment.			
Immunity test	**IEC60601 level test**	**Conformity level**	**Electromagnetic environment - guide**
Electrostatic _ _ discharge (ESD) IEC61 000-4-2	±6 contact kV ±8 kV air	±6 kV contact ±8 kV air	The floor must be wood, concrete or ceramic tile. If the floor is covered with synthetic materials, the relative humidity is at least 30%.
Frequency power (50 / 6 0 H z) magnetic field IEC61000-4- 8	3A/m	3A/m	The quality of electrical power should be like that of a commercial or hospital environment.
UT is the AC mains voltage before the application of the test level.			

Manufacturer's guidelines and declarations – electromagnetic immunity – for all non-life support equipment and systems

Manufacturer's guidelines and declarations – electromagnetic immunity			
This device is intended for use in the following electromagnetic environments. The customer using the tool must ensure that the tool is used in that environment.			
Immunity test	**IEC60601 Test level**	**Conformity level**	**Electromagnetic environment - guide**
Radiated RF	3 V / m 80 MHz to	3 V / m	Portable and mobile RF communications equipment must be used at a distance from these devices, including cables, with a minimum separation distance calculated from the equation corresponding to the frequency of the generator. Recommended separation distance $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz

			where P is the transmitter's maximum output power rating in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). The field strength of the fixed RF transmitter, as determined by the electromagnetic site survey, must be less than the compliance level in each frequency rangeb. Interference may occur in the vicinity of equipment marked with the following symbols: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/wireless) and mobile radio, amateur radio, AM and FM radio broadcasts, and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength at the location where the unit is used exceeds the applicable RF compliance level above, the unit must be

observed to verify normal operation. If abnormal performance is observed, additional measures may be required, such as unit reorientation or relocation.

[b] In the frequency range 150 kHz to 80 MHz, the field strength must be less than [3] V/m.

Recommended separation distance between portable and mobile RF communication devices and equipment or systems – for non-life-supporting devices or systems

Recommended separation distance between portable and mobile RF communication equipment and the unit	
The unit is intended for use in electromagnetic environments where radiated RF interference is controlled. The customer or user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and units as recommended below, according to the maximum output power of the communication equipment.	
Transmitter	Separation distance according to transmitter frequency (m).

maximum output power rating (W)	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.23
0.1	0.37	0.74
1	1.17	2.33
10	3.69	7.38
100	11.67	23.33

For transmitter ratings with maximum output power not listed above, recommended separation distance in meters (m) can be estimated using the equation applicable to the transmitter frequency, where P is the transmitter's maximum output power rating in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, separation distances apply for the higher frequency ranges.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

⚠ Warning ⚠

- Active medical devices must comply with EMC precautions and must be installed and used in accordance with these guidelines.
- Electromagnetic fields may affect the performance of the device, other equipment used near the unit must meet EMC requirements. Cell phones, X-rays, or MRI devices may be sources of interference, as they emit high-intensity electromagnetic radiation.
- Use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the device MANUFACTURER as replacement parts for internal components, may result in increased EMISSIONS or a decrease in EQUIPMENT or SYSTEM IMMUNITY.
- The device must not be used adjacent to or stacked with other equipment, if necessary, observe and verify that the device can operate normally in the configuration.
- The device or system may still be interfered with by other equipment, even if the other equipment meets the requirements of the relevant national standard.
- The device requires special precautions for electromagnetic compatibility (EMC) and requires qualified personnel to install and use in accordance with the EMC information given below.
- The device must not touch the connector pins marked with the ESD warning symbol, unless electrostatic discharge precautions are used, the device must not be connected to this connector.

- In order to avoid the accumulation of electrostatic charges, it is recommended to store, maintain and use the equipment at a relative humidity of 30% or more. Floors should be covered with ESD carpet or similar material. In the use of components, non-synthetic clothing should be worn.
- To prevent electrostatic discharge to ESD sensitive parts of the device, personnel should contact the metal frame of the component or a large metal object near the device. When using the device, especially where it is possible to contact ESD-sensitive parts of the device, the operator should wear a grounded wrist strap designed for ESD-sensitive devices. For more information on proper use, please refer to the instructions provided with the bracelet.
- All potential users are advised to understand the ESD warning symbols and receive training on ESD precautions.
- The most basic content of ESD prevention procedures training should include an introduction to the physics of electrostatic charges, voltage levels in conventional cases, and damage to electronic components when an operator with an electrostatic charge contacts them. In addition, methods to prevent electrostatic build-up, and the means and reasons for the discharge of static electricity from the human body to the ground or equipment frame or the use of wristbands to connect the human body to equipment or the ground before making the connection should be explained.

PT. SINKO PRIMA ALLOY

Alamat : Jl. Tambak Osowilangun Permai No. 61,
pergudangan osowilangun permai Blok E7-E8,
Surabaya-Indonesia (60191)

Telepon : 031-7482816

Fax. : 031-7482815

Aftersale (WA) : 0821-4281-7085

Email : aftersales@elitech.co.id
sinkoprima@gmail.com

Website : www.elitech.id